**The Mission of the Product Testing Laboratory is to provide our collaborators with accurate and timely information through optimal use of technology and resources.**

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**Technicians:**

Are responsible for the integrity of the test.

They ensure the correct and consistent testing/calibration process utilizing established procedures.

⬇

**Technical Leaders:**

Are responsible for the integrity of the test results from their laboratory.

They ensure results have been reviewed for consistency utilizing established procedures.

⬇

**Receiving & Reporting:**

Is responsible for the data integrity of the sample/request.

They provide a final check of our process and ensure all the test results for a sample correctly reflect the sample received.

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DOC CODE: P0622

ATTACHMENT 2

> ### Technicians:
> Are responsible for the integrity of the test.
> They ensure the correct and consistent testing/calibration process utilizing established procedures.

## Accountabilities

- Ensure correct & consistent calibration & testing based on procedures, work instructions, checklists & control charts.

- Ensure correct sample is tested & all associated analyses are requested.

- Review test results.
  Reject and recheck results.

## Recommendations

- Use work instructions at test stations (use will be audited and documented).*
  Follow control chart guidelines.*

- Compare to paperwork.*

- **Do not compare to Standard Deviation Limits.**

- Review data for too few # reps & inconsistent numbers. **Inconsistent numbers are a flag to look for an assignable cause, not criteria to recheck or reject.**

- **Reject data for assignable cause,** based on objective, defensible guidelines.*

- Document rejected data in computer notes editing.*

- Initiate recheck only if assignable cause indicates that data are invalid.

> **Technical Leaders:**
> Are responsible for the integrity of the test results from their laboratory.
> They ensure results have been reviewed for consistency utilizing established procedures.

| Accountabilities | Recommendations |
|---|---|
| • Ensure consistency of test results. | Review data that have been through ADAP* & are not automatically approved due to:<br>high sd*, outliers, incorrect # reps, or missing values, utilizing Status 50 & ToDo* reports.<br><br>Unapproved results are:<br>❶ investigated for assignable cause<br>❷ rechecked if:<br>   -assignable cause (or strong evidence) found, or<br>   -too few # reps, or<br>   -sd>2 x sd limit, to confirm<br>❸ else it is approved. |
| • Recheck and Document. | Request recheck (original values automatically rejected)<br>Enter in notes editing recheck reason & assignable cause, if applicable<br>Enter recheck info into lab notebooks.<br>When recheck completed:<br>❶ review results*<br>❷ recheck & document if assignable cause found (not for sd)<br>❸ else it is approved |
| • Ensure Technicians are trained on & are using Work Instructions. | • Review at least twice a year*<br>• Watch techs perform test after review to ensure procedural accuracy & document compliance. |

DOC CODE: P0622

ATTACHMENT 4

> ## Receiving & Reporting:
> ### Is responsible for the data integrity of the sample/request.
> ### They provide a final check of our process and ensure all the test results for a sample correctly reflect the sample received.

## Accountabilities

- Utilize knowledge of products, programs/projects & procedures
- Ensure accuracy of sample submissions (entry, samples/tests, barcodes, etc.)
- Ensure timeliness of completion
- Ensure integrity of sample/request data, **not product**- Review Preliminary Report

## Recommendations

- Stay current on procedures, work instructions, business awareness, collaborator communications
- Accurately capture quantity, priority, collaborator information, special instructions
- Monitor request in process (due dates vs. test completion)

**SD Warnings:**
If sd> 2 x sd limit
- Available information may confirm, or
- If already rechecked*, sd is confirmed, or
- If not rechecked
  - Investigate for assignable cause (sample mix-ups, system errors)
  - If enough sample, recheck

**Assessing Averages:**
Target Guidelines* - sample accuracy, and/or
Historical Data Results (hist. avg. ±3 hist. sd) - process trend, or
Neither (dev) - based on collaborator info, cigt construction knowledge

**Inter-relationships between tests:** (May confirm issues observed above)

If inter-relationships between tests do not explain questionable averages
- Available information may confirm, or
- If already rechecked, average is confirmed, or
- If not rechecked
  - Investigate for assignable cause (sample mix-ups, system errors)
  - If enough sample, recheck
- Contact collaborator if appropriate (based on program)